



# SAFETY DATA SHEET

Issuing Date 10-Mar-2021

Revision date 15-Sep-2020

Revision Number 1

## 1. Identification

### Product identifier

**Product Name** Sudocrem® Cosmetic Cream (EU)

**Product Code(s)** AL\_ILS1\_01788

### Other means of identification

**Proper shipping name** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

**UN number** UN3077

**Synonyms** Sudocrem® Healing Cream (Australia, New Zealand); Sudocrem® (Canada); Dermocrem® (Puerto Rico)

**Pure substance/mixture** Mixture

### Recommended use of the chemical and restrictions on use

**Uses/ Identified uses** Pharmaceutical

**Uses advised against** No information available

### Details of manufacturer or importer

#### Manufacturer

37 Epping Road  
Macquarie Park, NSW 2113  
Australia

Teva Corporate Headquarters  
5 Bazel Street PO Box 3190  
Petah Tikva, Israel

#### For further information, please contact

**Contact Point** Product Safety Department

**E-mail address** SDS.TevaIL@teva.co.il

### Emergency telephone number

**Emergency telephone number** United States/Canada/Puerto Rico: 1-800-424-9300 (Chemtrec) [24-hrs]  
International: +1-703-741-5970 (Chemtrec) [24-hours]

## 2. Hazard(s) identification

### GHS Classification

Not classified

### Label elements

**Hazard statements**

Not classified

**Other hazards which do not result in classification**

Toxic to aquatic life with long lasting effects

Harmful to aquatic life

**General Hazards****3. Composition/information on ingredients****Substance**

Not applicable

**Mixture**

Chemical Name	CAS No	Weight-%
Zinc Oxide	1314-13-2	Proprietary
Non-hazardous ingredients	Proprietary	Balance

**4. First-aid measures****Description of first aid measures**

<b>Emergency telephone number</b>	Poisons Information Center, Australia: 13 11 26 Poisons Information Center, New Zealand: 0800 764 766
<b>Inhalation</b>	Remove to fresh air.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
<b>Skin contact</b>	Wash skin with soap and water.
<b>Ingestion</b>	Clean mouth with water and drink afterwards plenty of water.

**Most important symptoms and effects, both acute and delayed**

**Symptoms** No information available.

**Indication of any immediate medical attention and special treatment needed**

**Note to physicians** Treat symptomatically.

**5. Fire-fighting measures****Suitable Extinguishing Media**

**Suitable Extinguishing Media** Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

**Unsuitable extinguishing media** No information available.

**Specific hazards arising from the chemical**

**Specific hazards arising from the chemical** Thermal decomposition can lead to release of irritating gases and vapors. Combustible material.

**Special protective actions for fire-fighters**

**Special protective equipment for fire-fighters** Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

**6. Accidental release measures****Personal precautions, protective equipment and emergency procedures**

**Personal precautions** Ensure adequate ventilation.

**For emergency responders** Use personal protection recommended in Section 8.

**Environmental precautions**

**Environmental precautions** See Section 12 for additional Ecological Information.

**Methods and material for containment and cleaning up**

**Methods for containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up** Take up mechanically, placing in appropriate containers for disposal.

**Precautions to prevent secondary hazards**

**Prevention of secondary hazards** Clean contaminated objects and areas thoroughly observing environmental regulations.

**Reference to other sections** See section 8 for more information. See section 13 for more information.

**7. Handling and storage****Precautions for safe handling**

**Advice on safe handling** Handle in accordance with good industrial hygiene and safety practice.

**Conditions for safe storage, including any incompatibilities**

**Storage Conditions** Keep in properly labeled containers. See product quality documents and/or label for the correct storage conditions of this product.

**Incompatible materials** None known based on information supplied.

**8. Exposure controls/personal protection****Control parameters****Exposure Limits**

Chemical Name	Australia	ACGIH TLV
Zinc Oxide 1314-13-2	10 mg/m <sup>3</sup> 5 mg/m <sup>3</sup> 10 mg/m <sup>3</sup> STEL	STEL: 10 mg/m <sup>3</sup> respirable particulate matter TWA: 2 mg/m <sup>3</sup> respirable particulate

		matter
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**Appropriate engineering controls**

**Engineering controls**                      Showers  
 Eyewash stations  
 Ventilation systems.

**Individual protection measures, such as personal protective equipment**

**Eye/face protection**                      No special protective equipment required.

**Skin and body protection**                      No special protective equipment required.

**Respiratory protection**                      No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

**Environmental exposure controls**                      No information available.

**9. Physical and chemical properties****Information on basic physical and chemical properties**

**Physical state**                      Cream/ Lotion; Liquid  
**Appearance**                      No information available  
**Color**                      No information available  
**Odor**                      No information available.  
**Odor threshold**                      No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
<b>pH</b>	No data available	None known
<b>Melting point / freezing point</b>	No data available	None known
<b>Boiling point / boiling range</b>	No data available	None known
<b>Flash point</b>	No data available	None known
<b>Evaporation rate</b>	No data available	None known
<b>Flammability (solid, gas)</b>	No data available	None known
<b>Flammability Limit in Air</b>		None known
<b>Upper flammability or explosive limits</b>	No data available	
<b>Lower flammability or explosive limits</b>	No data available	
<b>Vapor pressure</b>	No data available	None known
<b>Vapor density</b>	No data available	None known
<b>Relative density</b>	No data available	None known
<b>Water solubility</b>	No data available	None known
<b>Solubility(ies)</b>	No information available.	
<b>Partition coefficient</b>	No data available	None known
<b>Autoignition temperature</b>	No data available	None known
<b>Decomposition temperature</b>	No data available	None known
<b>Kinematic viscosity</b>	No data available	None known
<b>Dynamic viscosity</b>	No data available	None known
<b>Explosive properties</b>	No information available	
<b>Oxidizing properties</b>	No information available	

**Other information**

**Softening point**                      No information available  
**Molecular weight**                      No information available  
**VOC Content (%)**                      No information available  
**Liquid Density**                      No information available

**Bulk density** No information available

## 10. Stability and reactivity

### Reactivity

**Reactivity** No information available.

### Chemical stability

**Stability** Stable under normal conditions.

### Explosion data

**Sensitivity to mechanical impact** None.

**Sensitivity to static discharge** None.

### Possibility of hazardous reactions

**Possibility of hazardous reactions** None under normal processing.

**Hazardous polymerization** Hazardous polymerization does not occur.

### Conditions to avoid

**Conditions to avoid** Extremes of temperature and direct sunlight. Exposure to air or moisture over prolonged periods. Heat, flames and sparks.

### Incompatible materials

**Incompatible materials** Strong oxidizing agents.

### Hazardous decomposition products

**Hazardous decomposition products** None known based on information supplied.

## 11. Toxicological information

### Acute toxicity

### Information on likely routes of exposure

#### **Product Information**

**Inhalation** Specific test data for the substance or mixture is not available.

**Eye contact** Specific test data for the substance or mixture is not available.

**Skin contact** Specific test data for the substance or mixture is not available.

**Ingestion** Specific test data for the substance or mixture is not available

**Symptoms** No information available.

### Numerical measures of toxicity - Product Information

The following values are calculated based on chapter 3.1 of the GHS document

**ATEmix (oral)** 5,005.00 mg/kg

**Unknown acute toxicity** 100 % of the mixture consists of ingredient(s) of unknown toxicity  
98 % of the mixture consists of ingredient(s) of unknown acute oral toxicity

100 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity  
 100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)  
 100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)  
 100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

**Component Information**

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Zinc Oxide	> 5000 mg/kg ( Rat )	-	-

See section 16 for terms and abbreviations

**Delayed and immediate effects as well as chronic effects from short and long-term exposure**

<b>Skin corrosion/irritation</b>	No information available.
<b>Serious eye damage/eye irritation</b>	No information available.
<b>Respiratory or skin sensitization</b>	No information available.
<b>Germ cell mutagenicity</b>	No information available.
<b>Carcinogenicity</b>	No information available.
<b>Reproductive toxicity</b>	No information available.
<b>STOT - single exposure</b>	No information available.
<b>STOT - repeated exposure</b>	No information available.
<b>Aspiration hazard</b>	No information available.

**12. Ecological information****Ecotoxicity**

**Ecotoxicity** Toxic to aquatic life with long lasting effects. Harmful to aquatic life.

**Unknown aquatic toxicity** 97 % of the mixture consists of component(s) of unknown hazards to the aquatic environment.

Chemical Name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Zinc Oxide	IC50 (green algae): 0.17 mg/l; 72H	LC50 (rainbow trout): 1.1 mg/l; 96H	-	LC50 (Daphnia magna) >1000 mg/l;48h

**Persistence and degradability**

**Persistence and degradability** No information available.

**Bioaccumulative potential**

**Bioaccumulation** No information available.

**Mobility**

**Mobility in soil** No information available.

**Mobility** No information available.

**Other adverse effects**

**Other adverse effects** No information available.

### 13. Disposal considerations

**Waste treatment methods**

**Waste from residues/unused products** Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

**Contaminated packaging** Empty containers should be taken to an approved waste handling site for recycling or disposal.

### 14. Transport information

**ADG**

**UN number** UN3077  
**Proper shipping name** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
**Hazard class** 9  
**Packing group** III  
**Environmental hazard** Yes  
**Special Provisions** 274, 331, 335, 375, AU01  
**Description** UN3077, ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III

**IATA**

**UN number** UN3077  
**UN proper shipping name** Environmentally hazardous substance, solid, n.o.s.  
**Transport hazard class(es)** 9  
**Packing group** III  
**Description** UN3077, Environmentally hazardous substance, solid, n.o.s. (zinc oxide), 9, III

**IMDG**

**UN number** UN3077  
**UN proper shipping name** Environmentally hazardous substance, solid, n.o.s.  
**Transport hazard class(es)** 9  
**Packing group** III  
**EmS-No.** F-A, S-F  
**Special Provisions** 274, 335, 966, 967, 969  
**Marine pollutant** This product contains a chemical which is listed as a marine pollutant according to IMDG/IMO  
**Description** UN3077, ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide), Marine pollutant, 9, III

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

No information available

### 15. Regulatory information

**Safety, health and environmental regulations/legislation specific for the substance or mixture**

**National regulations**

**Australia**

See section 8 for national exposure control parameters

**Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)**

Classified as a scheduled poison according to the Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)

**Poison Schedule Number** 4**National pollutant inventory**

Subject to reporting requirement

Chemical Name	National pollutant inventory
Zinc Oxide - 1314-13-2	10 tonne/yr Threshold category 1

**International Inventories**

<b>TSCA</b>	Contact supplier for inventory compliance status.
<b>DSL/NDSL</b>	Contact supplier for inventory compliance status.
<b>EINECS/ELINCS</b>	Contact supplier for inventory compliance status.
<b>ENCS</b>	Contact supplier for inventory compliance status.
<b>IECSC</b>	Contact supplier for inventory compliance status.
<b>KECL</b>	Contact supplier for inventory compliance status.
<b>PICCS</b>	Contact supplier for inventory compliance status.
<b>AICS</b>	Contact supplier for inventory compliance status.

**Legend:****TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances**ENCS** - Japan Existing and New Chemical Substances**IECSC** - China Inventory of Existing Chemical Substances**KECL** - Korean Existing and Evaluated Chemical Substances**PICCS** - Philippines Inventory of Chemicals and Chemical Substances**AICS** - Australian Inventory of Chemical Substances**International Regulations****The Montreal Protocol on Substances that Deplete the Ozone Layer** Not applicable**The Stockholm Convention on Persistent Organic Pollutants** Not applicable**The Rotterdam Convention** Not applicable**16. Other information****Issuing Date** 07-Dec-2016**Revision date** 15-Sep-2020**Revision Note**

The symbol (\*) in the margin of this SDS indicates that this line has been revised.

**Key or legend to abbreviations and acronyms used in the safety data sheet**

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	Skin designation
C	Carcinogen		

**Key literature references and sources for data used to compile the SDS**

Agency for Toxic Substances and Disease Registry (ATSDR)

U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA)

EPA (Environmental Protection Agency)

Acute Exposure Guideline Level(s) (AEGl(s))

U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act  
U.S. Environmental Protection Agency High Production Volume Chemicals  
Food Research Journal  
Hazardous Substance Database  
International Uniform Chemical Information Database (IUCLID)  
Japan GHS Classification  
Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)  
NIOSH (National Institute for Occupational Safety and Health)  
National Library of Medicine's ChemID Plus (NLM CIP)  
National Library of Medicine's PubMed database (NLM PUBMED)  
National Toxicology Program (NTP)  
New Zealand's Chemical Classification and Information Database (CCID)  
Organization for Economic Co-operation and Development Environment, Health, and Safety Publications  
Organization for Economic Co-operation and Development High Production Volume Chemicals Program  
Organization for Economic Co-operation and Development Screening Information Data Set  
RTECS (Registry of Toxic Effects of Chemical Substances)  
World Health Organization

**Disclaimer**

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**End of Safety Data Sheet**